

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS
LIABILITY LITIGATION

MDL No. 2419
Dkt. No. 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:

Gilliam v. Chowdhury, M.D., et al.
1:15-cv-11367-RWZ

**PLAINTIFF’S MEMORANDUM OF LAW IN OPPOSITION
TO OHIO MEDICAL DEFENDANTS’ MOTION TO DISMISS**

I. INTRODUCTION

It is undisputed that the widespread outbreak of fungal meningitis which gave rise to this multi-district litigation was caused by contaminated preservative-free methylprednisolone acetate (“MPA”) compounded by New England Compounding Center, Inc. (“NECC”) and administered to patients at over 70 pain clinics, orthopedic practices and hospitals,¹ including by Dr. Chowdhury at the Marion Pain Clinic. Liability extends to the health care providers and facilities that purchased the contaminated products and distributed it to their patients. Despite extensive guidelines setting forth doctors’ and clinics’ responsibilities when outsourcing risky compounded drugs, defendants Dr. Batra, Dr. Katabay, Dr. Siddiqui, Ms. Chadha and Ms. Sheets (the “Ohio Medical Defendants”) failed to perform any due diligence. Instead, the Ohio Medical Defendants mail ordered hundreds of vials of prescription preservative-free MPA from NECC without any reasonable effort to assess and evaluate NECC’s ability to aseptically compound, package and dispense preservative free MPA.

¹ See CDC, Multistate Fungal Meningitis Outbreak Investigation, <http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html> (Visited March 2014); see also FDA, Multistate outbreak of fungal meningitis and other infections, <http://www.fda.gov/%20Drugs/DrugSafety/FungalMeningitis/default.htm>; Smith, Rachel M., et al., *Fungal Infections Associated with Contaminated Methylprednisolone Injections*, N Engl J Med 2013; 369:1598-1609 (Oct. 24, 2013).

Plaintiff is Sarah Gilliam, the daughter of the late Alice Thompson. On September 20, 2012, and October 4, 2012, Dr. Chowdhury, at the Marion Pain Clinic facility, performed epidural steroid injections (“ESI procedure”) on Ms. Thompson using NECC’s preservative-free MPA. Compl. ¶¶ 123-24. The MPA used during the ESI procedure was drawn from the vials that were part of the three lots of contaminated MPA recalled by NECC and the FDA on or about September 26, 2012, due to fungal contamination. *Id.* ¶ 125. As a direct and proximate result of the failure of Dr. Chowdhury and the Ohio Medical Defendants to properly investigate NECC’s compounding and sterilization practices, Ms. Thompson became ill in November 2012, December 2012 and again in February 2013, and was admitted for treatment of fungal meningitis. *Id.* ¶¶ 126-132. She died of her illness on March 6, 2013, due to fungal meningitis. *Id.* ¶¶ 133-134.

Plaintiff’s Complaint asserts claims for wrongful death, survival and loss of consortium. Compl. Counts X, XI and XII. The Complaint sets forth in detail the reasons why the Ohio Medical Defendants share responsibility for Plaintiff’s injuries and harm. But for their negligent and reckless conduct in mail ordering and purchasing contaminated steroids before first performing due diligence as to NECC, Ms. Thompson would not have received contaminated MPA and suffered serious illness and death.

The factual allegations in Plaintiff’s Complaint are nearly identical to the claims alleged against the “Clinic Related Defendants” in the Second Amended Master Complaint filed by the PSC and which have survived multiple motions to dismiss to date in this MDL.² Ms. Thompson’s claims have already survived a separate Motion to Dismiss filed by Dr. Chowdhury,

² The Second Amended Master Complaint [Dkt. No. 1719] lists a number of facilities that received recalled lots of MPA from NECC. Those hospitals, clinics, healthcare facilities, and their physicians, staff, agents, and employees are referred to in the Master Complaint collectively as the “Clinic Related Defendants.” Master Compl. ¶¶ 22-23. Marion Pain Clinic is among those facilities listed.

who is separately represented.³ The allegations against the Ohio Medical Defendants are well-pleaded, and sufficiently state claims upon which relief can be granted.

The Ohio Medical Defendants filed the instant Rule 12(b)(6) Motion to Dismiss (the “Motion”) seeking dismissal of each cause of action. One of the three substantive arguments advanced by Defendants, the need for the filing of an affidavit of merit, has already been decided by this Court’s previous decision in favor of Plaintiff.⁴

The second substantive issue advanced by Defendants, the claim that Ms. Thompson’s claim for wrongful death is subject to a one year statute of limitations, and is therefore time barred, is wrong as a matter of law. Defendants’ simply assume Ms. Thompson’s claim is one for medical negligence, rather than a claim for wrongful death, without citing any authority in support. Ohio Courts, including the Ohio Supreme Court, have considered the difference between a claim for medical negligence and one for wrongful death, even when the death results from the actions of health care providers, and have applied the two year statute of limitation set out in applicable Ohio law for wrongful death claims. Plaintiff’s claim was filed within the applicable two-year statute of limitations period.

Finally, Defendants’ claim that Plaintiffs’ claim for loss of consortium must be dismissed because a claim for wrongful death and loss of consortium cannot be asserted simultaneously. Again, Ohio courts have said otherwise. This Court has recognized in its order on Dr. Chowdhury’s motion to dismiss that Plaintiff’s claim for wrongful death and loss of consortium rise and fall together. Having upheld Plaintiff’s claim for wrongful death, Plaintiff should be allowed to maintain her claim for loss of consortium.

For the reasons set forth below, the Ohio Medical Defendants’ Motion to Dismiss should

³ See Memorandum of Decision dated July 28, 2015, Dkt. No. 2113.

⁴ *Id.* at 6-12.

be denied in its entirety.

II. STANDARD OF REVIEW

In deciding a motion to dismiss, “a court does not rule on the evidentiary sufficiency of a complaint, only on whether its factual and legal assertions allege ‘a plausible entitlement to relief.’”⁵ In considering a motion to dismiss, a court should “treat as true all well-pleaded facts, viewing those facts in the light most favorable to the plaintiff, and drawing all reasonable inferences therefrom for [plaintiff].”⁶ Under *Twombly*, a complaint need only allege “enough factual matter (taken as true) to suggest” the validity of the claim.⁷ “To justify a dismissal on any Civ. R. 12(b)(6) motion, the court must find beyond doubt from the complaint that the plaintiffs can prove no set of facts entitling them to relief.”⁸

To prove a claim for wrongful death on a theory of negligence, a plaintiff must show: (1) the existence of a duty owing to plaintiff’s decedent; (2) a breach of that duty; and (3) proximate causation between the breach of duty and the death.⁹

III. ARGUMENT

A. Plaintiffs’ claims are governed by the two year statute of limitations set forth in Ohio Rev. Code §2125.02 for wrongful death claims.

Ohio Rev. Code § 2125.01 establishes a cause of action for wrongful death:

When the death of a person is caused by wrongful act, neglect, or default which would have entitled the party injured to maintain an action and recover damages if death had not ensued, the person who would have been liable if death had not ensued . . . shall be

⁵ *Balerna v. Gilberti*, CIV.A. 09-10075-RGS, 2010 WL 4878286, at *4 (D. Mass. Nov. 24, 2010) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007)).

⁶ *Knowlton v. Shaw*, 704 F.3d 1, 3 (1st Cir. 2013) (citing *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir.2008)).

⁷ *Twombly*, 550 U.S. at 557.

⁸ *Saylor v. Providence Hosp.*, 113 Ohio App. 3d 1, 3-4 (1996).

⁹ *Littleton v. Good Samaritan Hosp. & Health Ctr.*, 39 Ohio St. 3d 86, 92 (1988).

liable to an action for damages, notwithstanding the death of the person injured . . .¹⁰

Section (D)(1) of Ohio Rev. Code § 2125.02, and not Ohio Rev. Code §2305.113(E)(3), establishes a statute of limitations applicable to claims for wrongful death. The statute provides that “a civil action for wrongful death shall be commenced within two years after the decedent’s death.”¹¹ There can be no question that Ms. Thompson’s claim was brought within two years after her death on March 6, 2013 resulting from Defendants’ failure to conduct adequate due diligence on NECC prior to treating her with NECC’s products.

Defendants’ Motion fails to address, or even acknowledge, that wrongful death claims under Ohio Rev. Code § 2125.01 are subject to a two year statute of limitations and simply assumes, incorrectly, that Ms. Thompson’s claim is a “medical claim” subject to the one year statute of limitations for medical malpractice. Defendants are wrong.

The Ohio Supreme Court, although never having decided this very issue, has drawn a stark contrast between claims for medical malpractice and those for wrongful death, even where the underlying facts stem from negligence in a medical setting.¹²

In *Daniel v. United States*, 977 F. Supp. 2d 777 (2013), the court analyzed whether it had subject matter jurisdiction over an Ohio wrongful death claim under the Federal Tort Claims Act. The claim arose out of medical treatment provided to the plaintiff’s husband that was alleged to have caused infection in his leg and eventually led to amputation and death. The Court had to decide whether Ohio’s four year statute of repose for “medical claims” would apply (barring plaintiff’s wrongful death claims) or whether the two year statute of limitations separately

¹⁰ Ohio Rev. Code § 2125.01

¹¹ Ohio Rev. Code § 2125.01 (D)(1).

¹² Plaintiff here addresses the distinction between a “medical claim” and a claim for wrongful death under Ohio Rev. Code § 2125.01 for purposes of addressing the issue of the adequacy of Plaintiff’s Complaint under Fed. R. Civ. P. 12(b)(6) and for no other purpose.

imposed by Ohio's wrongful death statute applied (permitting plaintiff's claims to proceed).

Upon analysis of the relevant Ohio case law, the *Daniels* court drew a sharp distinction between a "medical claim" as defined by Ohio's medical malpractice statute and claims under Ohio Rev. Code § 2125.01 for wrongful death. The *Daniels* court applied the two year statute for wrongful death claims.

In its analysis, the Court first dismissed the holding of *Fletcher v. University Hospital of Cleveland*, 172 Ohio App. 3d 153 (2007), *rev'd on other grounds*, 120 Ohio St.3d 167 (2008), that a wrongful death claim is a "medical claim" – noting that the *Fletcher* court "focused simply on the fact that a wrongful death claim was a suit against a hospital that 'arose out of the medical diagnosis or treatment of the decedent.'"¹³ The *Daniels* court pointed out that in overturning the state appellate decision in *Fletcher*, the Ohio Supreme Court specifically noted that the plaintiff in that case never cross-appealed the trial court's ruling that her wrongful death claim required an affidavit of merit because it was a "medical claim "so that the issue is not before us."¹⁴

Second, the *Daniels* Court looked to the Ohio Supreme Court's decisions in *Koler v. St. Joseph Hospital*, 69 Ohio St. 2d 477 (1982). In *Koler*, the plaintiff filed a wrongful death suit against her late husband's doctors and his treating hospital claiming their medical care caused his death. The defendants in *Koler* argued that a wrongful death claim was a statutorily defined "medical claim" because it was a suit against a hospital. In rejecting that argument, the Ohio Supreme Court explained there is a deep division between a malpractice claim and a wrongful death claim under Ohio law:

Although originating in the same wrongful act or neglect, the two claims are quite distinct, no part of either being embraced in the other. One is for a wrong to the injured person and is confirmed to

¹³ *Daniels*, 977 F. Supp. at 781.

¹⁴ *Id.* (citing *Fletcher*, 897 NE.2d at n.2).

his personal loss and suffering before he died, while the other is for the wrong to the beneficiaries and is confined to their pecuniary loss through his death.¹⁵

Finally, the *Daniels* court looked to the Ohio Supreme Court's discussion in *Klema v. St. Elizabeth's Hosp. of Youngstown*, 170 Ohio St. 519 (1960). The plaintiff in *Klema* brought a wrongful death suit against her late husband's hospital for failure to administer sufficient anesthesia during a medical procedure, resulting in his death. The court was required to determine if the case was governed by the one year statute of limitations applicable to "medical claims" or the two year statute of limitations for wrongful death claims in Ohio. The court concluded that, absent clear legislation to the contrary, wrongful death actions were governed only by provisions in the wrongful death statute.¹⁶

There is no definitive case law to suggest a wrongful death claim against a doctor or other health care provider is a "medical claim" as Defendants wrongly assume. As in *Klema*, without clear legislation to the contrary, there is nothing to suggest that Plaintiff's claim for wrongful death is to be construed as a "medical claim" as defined by the statute related only to claims for medical malpractice. As the Ohio Supreme Court indicated in the circumstances presented in *Klema*, if the Ohio legislature wished to define wrongful death claims against doctors or hospitals as "medical claims" for purposes of the applicable statute of limitations, they could and would have clearly specified that intent.¹⁷ They have not. This Court should not, as Defendants' argument suggests, impose a one-year statute of limitations on a claim for wrongful death when the Ohio legislature has clearly established a two year limitations period.

¹⁵ *Id.* at 782 (citing *Koler*, 432 N.E.2d at 823) (additional citations omitted).

¹⁶ *Klema*, 166 N.E. 2d at 769.

¹⁷ *Id.*

B. Plaintiff's claim for loss of consortium may be maintained alongside a claim for wrongful death.

Defendants' assertion that claims for wrongful death and loss of consortium cannot be brought simultaneously is incorrect. In its decision concerning Dr. Chowdhury's motion to dismiss, this Court previously acknowledged that the claim for loss of consortium asserted by Plaintiff survives if the underlying principle claim for wrongful death survives.¹⁸

Defendants cite a single case, *Lykins v. Miami Valley Hospital*, Montgomery C.P. No. 00-CV-2404, 2001 WL 35673997, an unpublished summary judgement opinion, to support their contention that Plaintiffs' loss of consortium claims must be dismissed. However, Ohio Courts consistently hold that a claim for wrongful death and a claim for loss of consortium are separate and distinct claims and not mutually exclusive. For example, in *Distelhorst v. Great American Insurance Co.*, the Court of Appeals of Ohio considered the question of whether claims for medical expenses and loss of consortium are merged with claims for wrongful death. There plaintiff had brought claims for wrongful death and survivorship as well as a claim for wrongful death. The trial court rejected defendant's argument that plaintiff's claim for medical expenses and loss of consortium is not a separate and distinct claim from those for wrongful death. The Court of Appeals of Ohio agreed.

[T]he damages recoverable for the wrongful death of a victim are unrelated to a claim for medical expenses or a claim for loss of consortium . . . A person can assert a claim for medical expenses and loss of consortium when an injured person recovers from an accident. Thus, in the absence of any contract language to the contrary, appellant's argument that the claims merge is unfounded. . . . Accordingly, the trial court properly found that appellant has three separate and distinct claims; the claim of the estate of [the deceased] for wrongful death, the claim of the estate [of the

¹⁸ See Memorandum of Decision dated July 28, 2015 [Dkt. No. 2113] at 12 (citing *Stratford v. SmitKline Beecham Corp.*, No. 2:07-cv-639, 2008 WL 2491965, at *9 (S.D. Ohio June 17, 2008, *Campbell v. PMI Food Equip. Grp., Inc.*, 509 F.3d 776, 790 (6th Cir. 2007); *Bowen v. Kil-Kare, Inc.*, 585 N.E.2d 384, 392 (Ohio 1992)).

deceased] for survivorship, and the claim of the [surviving spouse] for loss of consortium and medical expenses.¹⁹

Here, as in *Distelhorst*, Plaintiff may maintain a claim for both wrongful death and for loss of consortium and Defendants' Motion should be denied.

IV. CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that this Court deny the Ohio Medical Defendants' Motion to Dismiss in its entirety. In the alternative, should this Court determine that Plaintiff's allegations are deficient, Plaintiff respectfully requests the opportunity to amend her complaint to provide further allegations.

Dated: September 18, 2015

Respectfully submitted,

/s/ Thomas M. Sobol

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¹⁹ *Distelhorst v. Great American Insurance Co.*, 1987 WL 27823 (Ohio 1987) at *3.

CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: September 18, 2015

/s/ **Thomas M. Sobol**
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